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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/686,737	10/10/2000	Junquan Xu	ART-00102.P.1	7112
24232 7	7590 03/13/2003			·
DAVID R PRESTON & ASSOCIATES			EXAMINER	
SUITE 205	BLUFF DRIVE		DO, PENSEE T	
SAN DIEGO,	CA 92130		ART UNIT	PAPER NUMBER
	,	·	1641 DATE MAILED: 03/13/2003	0

Please find below and/or attached an Office communication concerning this application or proceeding.

•	Application N .	Applicant(s)			
Offic Action Summary	09/686,737	XU ET AL.			
One Action Canimary	Examiner	Art Unit			
- The MAIL ING DATE of this communication and	Pensee T. Do	correspondenc address			
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Peri d for Reply					
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).  Status					
1) Responsive to communication(s) filed on 19 E	<u> December 2002</u> .				
2ā)☐ This action is <b>FiNAL</b> . 2b)⊠ Thi	s action is non-final.				
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. <b>Disposition of Claims</b>					
4) Claim(s) <u>1-3,7-19,21,26-32,34,41-47,51,52 and 57-60</u> is/are pending in the application.					
4a) Of the above claim(s) is/are withdrawn from consideration.					
5) Claim(s) is/are allowed.	+ ii	•			
6)⊠ Claim(s) <u>1-3,7-19,21,26-32,34,41-47,51,52 and 57-60</u> is/are rejected.					
7) Claim(s) is/are objected to.					
8) Claim(s) are subject to restriction and/or	election requirement.				
Application Papers					
9) The specification is objected to by the Examiner.					
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.					
Applicant may not request that any objection to the					
11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner.  If approved, corrected drawings are required in reply to this Office action.					
12) The oath or declaration is objected to by the Examiner.					
Priority under 35 U.S.C. §§ 119 and 120					
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).					
a) ☐ All b) ☐ Some * c) ☐ None of:					
1. Certified copies of the priority documents have been received.					
2. Certified copies of the priority documents have been received in Application No					
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.					
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).					
a) ☐ The translation of the foreign language provisional application has been received.  15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.					
Attachment(s)					
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s)	5) Notice of Informa	ry (PTO-413) Paper No(s) I Patent Application (PTO-152)			

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# **DETAILED ACTION**

## Election/Restrictions

Applicant's election with traverse of group II, claims 15-19, 21, 26-32, 34, 41-47, 51, 52, 54, and 57-60, in Paper No. 9 is acknowledged. The traversal is on the ground(s) that the claims of the two groups are connected by a single, searchable unifying relationship that connects the claims in design. Thus, there would not be a serious burden for searching and examining the claims together in a single application. This is found persuasive. Thus, the claims are rejoined.

The requirement is still deemed proper and is therefore made FINAL.

# Claims Status

Claims 1-3, 7-19, 21, 26-32, 34, 41-47, 51, 52, 54, 57-60 are pending.

# Information Disclosure Statement

The IDS filed on May 5, 2000 is entered. However, there is no document found.

Please resubmit the copies contained in this IDS for consideration.

# Specification Objections

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Claims 13 and 14 are objected because they recite a negative limitations. Support for such limitations is required.

Claim Rejections - 35 USC § 112

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Claims 2, 7-14, 26, 41 and 42, 44-46, 52, 57-60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is indefinite for reciting "low osmolarity". What are metes and bounds of "low" osmolarity?

Claim 26 is indefinite because "blood sample" lacks antecedent basis. "Blood sample" has not been introduced in claim 21 or 15.

Claims 41 and 42 depend from a canceled claim 35.

# Claim Rejections – 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States
- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1,15-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Ebersole et al. (US 5,578,460).

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Ebersole teaches a electrophoretic method for the separation of viable mixtures of viable cells including bacterial cells for analysis of microbial communities. A sample of a mixture of cells is introduced into a capillary tube that has been filled with an electrically conductive solution. As an electric field is applied to the capillary, both electroosmotic and electrophoretic movements are created, resulting in the separation of the viable cell mixture based on their differences in their charge and mass. The capillary tube is filled with an electrolyte separation buffer. The electrode buffer may be of the same or different composition as that contained in the sample, and it may contain agents to modulate the electroosmotic flow velocity, or to improve the resolution of the cell separation. Generally, electrophoretic buffer must be electrically conductive, facilitate electroosmosis flow and preserve the physiological integrity of the cells. Buffer concentrations can range from 10 um to 250 mM. High buffer molarity can result in high currents that can create excessive Joule heat which can disrupt the separation. Thus, low buffer molarity is preferred. The buffer contains sufficient electrolyte to produce a conductive path within the capillaries in which the separation is to occur. Bacteria mixture used are Streptococcus pneumoniae, Staphylococcus aureus which are disease causing agents (etiological agents). A lower molarity of sample buffer of the same type as the separation buffer may also aid in sample stacking or narrowing the sample plug width (see col. 6, lines 24-col. 65; col. 13, line 51-col. 13, line 14; col. 15, lines 9-12).

Claims 1, 3, 15-19, 21, 27, 28, 30, 31, 32, 34, 43, are rejected under 35 U.S.C. 102(e) as being anticipated by Cheng et al. (US 6,280,590).

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Cheng teaches devices and methods for performing channel-less separation of cell particles by dielectrophoresis, separation of desired components from crude mixtures such as cell lysates, and/or enzymatic reaction of such lysates, all of which can be conducted on a single bioelectronic chip. The bioelectronic chip is a microfabricated silicon chip on a printed circuit board and a flow cell mounted on the chip to form a flow chamber. The chip includes a piurality of circular microelectrodes which are preferably coated with a protective permeation layer which prevents direct contact between any electrode and a sample introduced into the flow chamber. (see col. 4, line 50-col. 5, line 15). One example method of using such device includes preparation of a cell sample for introduction (e.g. suspension in a cell separation buffer) and subsequent dielectrophoresis; introduction of the sample into the flow cell (e.g. via pumping); subjecting the sample to an electric field to dielectrophoretically separate the desired cells from the sample. A cell separation buffer comprising 0.05x TBE (4.5 uM Tris, 4.5 uM boric acid, 0.1 uM EDTA, pH 8.2), 250 mM sucrose, pH 8.2, was prepared. The conductivity of the buffer was 114 uS/cm measured by an Accumet pH meter 50. The conductivity under which cell separation was carried out was chosen carefully to ensure that the desired cells were subjected to positive electrophoresis and all normal human blood cells were subjected to negative dielectrophoresis. (see col. 8, line 60-col. 9, line 10). In another embodiment, to perform the dielectrophoretic separation of E. coli cells from blood cells in the cell culture, an unused cartridge was employed. The chip of the cartridge was first washed by pumping a separation buffer (sample solution) from a sample/buffer reservoir through a tubing and flow cell. Next, the cell culture was

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pumped into the flow cell and the pump was switched off. The entire array of electrodes were addressed in a checkerboard bias format providing field maxima at each electrode and field minima in the areas between the electrodes. (see col. 10, lines 40-50). After separation, assay is carried out to detect the desired component in the separated cells. Thus, binding agent must be coupled to one component in the sample for the assay. (see col. 11, line 62-col. 12, line 8).

# Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cheng et al. (US 6,280,590).

Cheng has been discussed above.

However, Cheng fails to teach adding the sample to the chamber before the sample solution is added to said chamber.

It would have been obvious to alternate the order of adding the sample and the sample solution to the flow chamber because regardless of the order in which the sample or sample solution is added to the chamber, the result would be the same. No unexpected result would be achieved.

#### Remarks .

Claims 41 and 42 are unsearchable because they depend from a canceled claim.

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Claims 2, 7-14, 44-46, 51, 52, 57-60 are free of prior arts.

The prior art does not teach a sample solution that when mixed with the sample selectively modifies at least one dielectric property of at least one component of said sample and has a conductivity such that one or more moieties of said sample can be separated using dielectrophoretic forces; wherein the sample solution has a low osmolarity.

# Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 703-308-4398. The examiner can normally be reached on Monday-Friday, 7:00-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-746-5291 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Pensee T. Do Patent Examiner March 10, 2003 CHRISTOPHER L. CHIN PRIMARY EXAMINER GROUP 1800

Christyl L. Ol.